



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/506,988	02/18/00	TANG	J OMRF 176

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Patrea L Pabst  
Arnall Golden & Gregory LLP  
2800 One Atlantic Center  
1201 West Peachtree Street  
Atlanta GA 30309-3450

EXAMINER
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SEAMAN, D

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/506,988

Applicant(s)

TANG ET AL.

Examiner

D. Margaret Seaman

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.

- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_.

DETAILED ACTION

1. This application was filed 18 February 2000 and claims priority to 60/120,835, filed 19 February 1999. Claims 1-12 are before the Examiner.

*Claim Rejections - 35 USC § 112*

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it is not seen where the instant specification enables the ordinary artisan to determine what compounds would fit the instant claims other than the specific compound that is labeled UIC-98-056. As far as enablement goes, the only transition-state isostere that the instant specification teaches is  $\text{CH}(\text{OH})\text{-CH}_2$ . The specification does not enable any other compound other than UIC-98-056 that is bounded by all of the instant claims. It would require undue experimentation for the ordinary artisan to make/use the instant invention without further guidance as to the meets and bounds of the claims.

4. Claims 1-12 are rejected under 35 USC § 112, first paragraph, as having a lack of written description. Specifically, the specification does not describe what a "transition-state isostere" is other than the one specified CH(OH)-CH<sub>2</sub>. Without knowing what the instant invention needs, the ordinary artisan would find it close to impossible to find a compound that would fit within the bounds of the instant claim 1. What is a transition-state isostere? What compounds other than the specified UIC-98-056 would fit the boundaries of claim 1?

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-12 are ambiguous due to the phrase "transition-state isosteres". The only definition of this is the moiety CH(OH)-CH<sub>2</sub>. A chemical dictionary defines an isostere however, it is unclear as to how an isostere can be a transition-state isostere. What other transition-state isosteres are encompassed by claim 12?

Claims 3-4 are ambiguous due to the compound having the ability to inhibit an "aspartic acid protease". Is there more than one aspartic acid protease? If so, do the instantly claimed compounds inhibit all of these proteases or just a few?

Claims 5 and 11 are ambiguous due to the claim having "UIC-98-056" as the compound. This appears to be a name for the compound could possibly change over time. It would be more appropriate if the compound be named by its chemical name or structure.

*Claim Rejections - 35 USC § 102*

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.


8. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Carroll (1) (Bioorg Med Chem Lett 8, 1998, 2315-2320), Carroll (2) (Bioorg Med Chem Lett 8, 1998, 3203-3206) and Baldwin (Structural biology 2(3), 1995, 244-249).

Carroll (1) teaches (see page 2316) core structures in table 1 wherein R4 is (13) that have two of the same groupings identified as transition-state isosteres (CH(OH)-CH<sub>2</sub>).

Carroll (2) teaches (see page 3203) PL 792 having three groupings of C(O)NH that would appear to fit within the instantly claimed invention.

Baldwin teaches (see page 244) compound A-77003 having the grouping CH(I-Pr)-C(O) twice in the compound having HIV protease inhibition qualities.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 703-308-4528. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
D. Margaret Seaman  
Primary Examiner  
Art Unit 1625

dms  
September 7, 2000